UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICA N.V., and JANSSEN PHARMACEUTICA PRODUCTS, L.P.,	
Plaintiffs,	
v.	CIVIL ACTION NO. 03-6220 (JCL)
MYLAN PHARMACEUTICALS, INC.,	**MEMORANDUM & ORDER**
Defendant.	

LIFLAND, District Judge

Before the Court is the appeal of Defendant Mylan Pharmaceuticals Inc. ("Mylan") from the June 29, 2005 Order of former United States Magistrate Judge Haneke denying Mylan's motion to compel discovery and granting Plaintiffs Janssen Pharmaceutica N.V. and Janssen Pharmaceutica Products, L.P. ("Janssen") a protective order. For the reasons stated herein, the Court will vacate the Order denying Mylan's motion to compel and granting Janssen a protective order.

BACKGROUND

This is a Hatch-Waxman[1] case involving risperidone, an anti-psychotic drug.

[1] The Hatch-Waxman Act is officially called the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 et seq.

Janssen owns the patent for risperidone (the "'663 patent") which it sells in the United States under the trade name of Risperdal. Mylan[2] filed both an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") to market generic versions of Risperdal, and a Paragraph IV Notice[s] certifying that the '663 patent is invalid and would not be infringed by the proposed generic product. In response, Janssen filed a patent infringement suit against Mylan on December 29, 2003.

The dispute that is the subject of this appeal centers on whether Janssen must produce the Investigational New Drug Application ("IND") and the New Drug Application ("NDA")[3] which Janssen filed with the FDA to demonstrate that Risperdal was safe and effective. Mylan argues that Janssen must produce these applications because they are relevant to Mylan's defenses of invalidity and inequitable conduct.

In its initial production requests of March 22, 2004, Mylan requested the following two documents:

62. All documents and things relating to communications between

---

[2] Dr. Reddy's Laboratories ("DRL") also filed an ANDA and a Paragraph IV Notice[s]. Dr. Reddy's Laboratories is the Defendant in Civ. Action No. 03-6185 (JCL), a separate patent infringement suit filed by Janssen in this Court.

[3] The NDA must identify all relevant Drug Master Files ("DMF").

> Janssen and the FDA or any other regulatory Authority regarding Risperidone, Compound 11, Pirenperone or Ketanserin.
>
> 75. All documents relating to any NDA for any oral tablet containing Risperidone.

Janssen made standard objections to these requests under Fed. R. Civ. P. 34, and agreed to "produce responsive documents to the extent they have not already been produced to Mylan."

Discovery proceeded, and Mylan was only able to find a small, redacted portion of the NDA and no IND or DMFs. After failed attempts to acquire complete copies of the applications from Janssen, Mylan petitioned Magistrate Judge Haneke via letter dated March 16, 2005 for assistance in resolving the discovery dispute. Judge Haneke instructed Janssen to produce the portions of the NDA and the IND that were relevant to Mylan's defenses. Nevertheless, Mylan continued to be unsuccessful in its efforts to obtain copies of the relevant portions of the NDA and the IND.

At a status conference on June 15, 2005 Judge Haneke reversed his earlier instructions and ruled that Mylan could not have any access to the NDA and the IND. An Order of June 29, 2005 memorializes this ruling. As part of this Order, Judge Haneke also granted Janssen a protective order, and denied Mylan's motion to compel production of missing "clinical investigation documents" on pirenperone, or to have

Janssen explain these documents' disposition. Pirenperone is another anti-psychotic drug and prior art of which Janssen advised the Patent and Trademark Office when it was prosecuting the '663 patent. Janssen does not dispute the relevancy of this discovery, but asserts that it has produced every document it was able to locate regarding pirenperone. Mylan now appeals Judge Haneke's order.

STANDARD OF REVIEW

The parties dispute the appropriate standard of review in this case. Under the Federal Magistrates Act of 1968, a Magistrate Judge may decide certain non-dispositive pretrial matters which a district court may reconsider and then reverse if it finds the ruling to be "clearly erroneous or contrary to law." 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A); see also Haines v. Liggett Group, Inc., 975 F.2d 81, 92 (3d Cir.1992). Where a Magistrate Judge has ruled on a non-dispositive discovery order, some courts apply a third "abuse of discretion" standard of review. In re Gabapentin Patent Lit., 312 F. Supp. 2d 653, 661 (D.N.J. 2004). In contrast, a district court's review of a Magistrate's ruling that is dispositive of a party's claim or defense is *de novo*. See 28 U.S.C. § 636(b)(1)(C); Fed. R. Civ. P. 72(b); National Labor Relations Board v. Frazier, 966 F.2d 812, 816 (3d Cir. 1992).

Here, Mylan argues that Judge Haneke's Order must be reviewed *de novo*.

Without the NDA and IND, Mylan argues that it will not be able to prove an inequitable conduct defense[4] by showing that the information Janssen disclosed to the FDA differs from the information Janssen disclosed to the Patent and Trademark Office. Therefore, the Order effectively disposes of one of Mylan's defenses. Janssen responds that denying Mylan the NDA and IND does not dispose of its inequitable conduct defense because Mylan has other ways of developing this defense, such as through depositions of the inventor and the attorneys who prosecuted patent '663. According to Janssen, calling the denial of discovery in this case a "dispositive issue" would make every discovery motion "dispositive."[5]

Although many discovery orders may be non-dispositive, the effect, rather than the type, of the motion is an important inquiry for determining the appropriate standard of review. See, e.g., Frazier, 966 F.2d at 817. An order that strikes a

---

[4] Mylan also argues that its invalidity defense will be "unfairly hampered" without discovery of the NDA and the IND. (Def. Br. at 16) Because the Court will grant discovery based on the inequitable conduct defense, it need not address this argument.

[5] Janssen also argues that Mylan's failure to plead an inequitable conduct defense undermines, if not destroys, Mylan's arguments in the instant motion. Mylan responds that it cannot plead an inequitable conduct defense without the NDA and the IND because an inequitable conduct defense "must be pled with particularity." See, e.g., Ferguson Beauregard/Logic Controls v. Mega Systems, LLC, 350 F.3d 1327, 1344 (Fed. Cir. 2003). The Court agrees with Mylan that the discovery is relevant to its planned inequitable conduct defense. If need be, Mylan may make a motion to amend its answer at a later date.

defendant's affirmative defense is dispositive of that defense and therefore requires *de novo* review. See Starlever Hydraulik v. Mohwak Res. Ltd., 1996 WL 172712, at *4 (N.D.N.Y. 1996); Central States, Southeast & Southwest Areas Pension Fund v. Landvatter, 1992 WL 93227, at *1 (N.D. Ill. 1992). Here, the effect of Judge Haneke's Order precluding Mylan from discovering the NDA and the IND is to strike Mylan's inequitable conduct defense. Without knowing what Janssen told the FDA, Mylan will not be able to prove if Janssen acted inequitably in disclosing inconsistent information to the Patent and Trademark Office. Therefore, Judge Haneke's Order denying Mylan discovery of the NDA and the IND amounts to a dispositive order that the Court will review *de novo*.[6]

ANALYSIS

It is axiomatic that a party has a right to discovery of any facts relevant to any party's claims or defenses. Fed. R. Civ. P. 26(b)(1). Here, the discovery of the NDA and the IND are not only relevant, but essential, to Mylan's potential defense of inequitable conduct. See, e.g., Bruno Indep. Living Aids, Inc. v. Acorn Mobility Services, Ltd., 394 F.3d 1348, 1351-52 (Fed. Cir. 2005) (affirming a finding of

[6] The Court notes that even if it treated Judge Haneke's order as non-dispositive, and applied a "clearly erroneous, "contrary to law" or "abuse of discretion" standard of review, its decision in the instant matter would be the same.

inequitable conduct where the patentee withheld prior art from the Patent and Trademark Office that had been submitted to the FDA). Janssen argues that Judge Haneke was correct in denying Mylan's motion to compel because the drug applications are irrelevant and because Mylan's motion was untimely. Both of these arguments are without merit.

Janssen argues that the applications are irrelevant because "this case is about the infringement and validity of Janssen's '663 patent - not about Janssen's NDA/IND." (Pl. Br. at 16) This rationale makes no sense because the infringement and the validity of the patent depend in part on the NDA and IND Janssen submitted to the FDA. Moreover, Mylan requested discovery of these drug applications in March of 2004. Although Mylan did not request Judge Haneke's intervention until March of 2005, Mylan did not wait to file its motion for the purpose of being dilatory, but rather to try to resolve the issue without judicial intervention. Even Judge Haneke recognized the need for this discovery of the applications when he allowed Mylan to discover relevant parts of the NDA and the IND in March of 2005. His reasons for reversing that decision, and denying Mylan's motion to compel in June of 2005, are unclear and without foundation.

Concerning the documents on pirenperone, Mylan argues that Janssen has only produced documents concerning the drug's anti-anxiety and not anti-psychotic

properties. Mylan argues that there must be more documentation on the testing of pirenperone and its anti-psychotic properties because Janssen told the Patent and Trademark Office that pirenperone was prior art and being extensively tested as an anti-psychotic agent when Janssen was prosecuting its '663 patent. Janssen asserts that is has produced all documents in its possession related to pirenperone. Nonetheless, it is appropriate to have an Order in place requiring production if such documents do turn up. The Court will vacate Judge Haneke's protective order relating to pirenperone. Further discovery on issues related to pirenperone is subject to the discretion of Magistrate Judge Falk.

Accordingly, **IT IS** on this 10th day of February, 2006,

ORDERED that the June 29, 2005 Order of Magistrate Judge Haneke is vacated; and it is further

ORDERED that Janssen is to produce within fourteen days of this Order all documents and things relating to any Investigational New Drug Application (IND), New Drug Application (NDA), and/or Drug Master File (DMF) regarding Risperdal tablets that are in its possession, custody or control; and within twenty-eight days of such production to provide Rule 30(b)(6) testimony as to the preparation and filing with the U.S. Food and Drug Administration (FDA) of such documents and things; after receiving such documents and things and all final transcript(s) of such

testimony, Mylan shall have forty-two days to supplement its expert reports with regard to same, with Janssen having fourteen days after such supplementation to produce responsive expert reports on same, and any expert depositions on same to be conducted within fourteen days after any such responsive reports.

ORDERED that further discovery related to pirenperone is subject to the discretion of Magistrate Judge Falk.

\s\ John C. Lifland, U.S.D.J.